OCT 7 - 2004 K042401

510(k) Summary

Degage's
Vari-Able APB Manual Wheelchair

Submitter's Name, Address, Telephone Number, Fax Number, Contact Person, and Date Prepared:

American Track Roadsters, Inc. dba Degage
3535 South Kipling Parkway
Lakewood, CO 80235
Phone (303) 986-9300
Fax (303) 986-9301

Contact Name: Greg Peek, President

Date Prepared: August 27, 2004

Name of Device and Name/Address of Sponsor:
American Track Roadsters, Inc. dba Degage
3535 South Kipling Parkway
Lakewood, CO 80235
Phone (303) 986-9300
Fax (303) 986-9301

Device Name: Vari-Able APB

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 891OR

Predicate Device: Labac MTC (K921136)

Intended Use:
The intended use of the Vari-Able, APB (Adaptable Positioning Base) mechanical wheelchair is to provide mobility to personswith a primary pediatric indication who are limited to a sitting position.

Technological Characteristics and Substantial Equivalence:

Device Description:
The Vari-Able, APB (Adaptable Positioning Base) is a manually operated, attendant controlled, manual, mechanical wheelchair and patient positioning system. It is designed to provide mobility and optimized positioning for patients who require long term accommodationdue to conditions of severe physical motion restriction. Patients with diagnosis such as cerebal palsy, would typically benefit from

the use of the Vari-Able, APB (Adaptable Positioning Base).

The product consists of a steel/aluminum frame, rear wheels (which can be substituted based on patient requirements), a seat pan, front wheels for steering and support, and other components such as brakes, anti-tip wheels, footrests, and manual adjustments for seating configuration, and manual positioning adjustment of the tilt angle. While a seat pan and back panel are provided, the APB will accept various types of wheelchair cushions and seating systems currently available in the market.

The product is capable of many configurations of the frame, wheels, and components to accommodate patients with difficult to solve positioning requirements. Using manual adjustments that can be made by hand or with traditional hand tools, various heights and angles of the chair may be changed to accommodate the patient's needs.

The Vari-Able APB (Adaptable Positioning Base) also features weight shifting capabilities using a "Tilt-in-Space" mechanism to prevent development of Decubitus Ulcers. This also can assist in positioning and feeding.

The product is designed to function indoors or outdoors on surfaces such as sidewalks and other public places.

Substantial Equivalence:
The Vari-Able APB is substantially equivalent to the Labac MTC (K921136) due to similarities in materials, construction, configuration, indications, and use.

Both devices are manually operated by the user or an attendant. Both devices provide mobility to persons limited to a sitting position. Both devices are constructed of a tubular frame, four wheels (two large rear wheels, and two small front wheels for steering). Both devices feature a manual tilt-in-space mechanism and other configuration options that provide adjustment to maximize user comfort and positioning.

Performance Data:
The Vari-Able APB and the Labac MTC were tested using a methodology based on ANSI/RESNA Wheelchair Standards Volume 1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters), Sections 1 and Section 5. Comparison of tiltover tests performed laterally, posteriorly, and anteriorly indicate the two devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. Gregory A. Peek
President
American Track Roadsters, Inc.
Degage
3535 South Kipling Street
Lakewood, Colorado 80235

Re: K042401
Trade/Device Name: Vari-Able, APB Mechanical Wheelchair
Regulation Number: 21 CFR 890. 3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: September 16, 2004
Received: September 20, 2004

Dear Mr. Peek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 042401

Device Name: Vari-Able, APB Mechanical Wheelchair

Indications for Use:

The intended use of the Vari-Able, APB (Adaptable Positioning Base) mechanical wheelchair is to provide mobility to persons with a primary pediatric indication who are limited to a sitting position.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042401